IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)))))))))))	**Civil No. 04-12457 PBS**

DePuy Mitek Bench Memorandum Regarding Request for Adverse Inference Instruction Based on Arthrex's Failure to Preserve Evidence

Mitek will request a post-trial jury instruction that, because of defendants' failure to preserve evidence, the jury may draw an inference that the destroyed information was unfavorable to Arthrex.

The pivotal issue in this case is whether the coating on FiberWire sutures has a material effect on the basic and novel characteristics of the claimed suture. Defendants retained at least two different experts and provided reports and testimony in purported support of their position that the coating on FiberWire materially affects the novel and basic characteristics of the claimed invention.

- Dr. Gitis was retained to perform tests to evaluate the surface frictional properties of so-called "coated" and "uncoated" FiberWire.
- Dr. Burks was retained to perform a tactile feel test on so-called "coated" and "uncoated" FiberWire sutures.

Both experts failed to properly preserve data generated from or information relating to their tests. Under the circumstances, Mitek is entitled to an adverse inference jury instruction that the destroyed testing data or information was unfavorable to Arthrex's position, and respectfully requests that the Court instruct the jury as follows:

> You have heard testimony about evidence which has not been produced. Counsel for plaintiff has argued that this evidence was in defendant's control and would have proven facts material to the matter in controversy.
>
> If you find that the defendant could have produced the evidence and that the evidence was within its control, and that the evidence would have been material in deciding among the facts in dispute in this case, then you are permitted, but not required, to infer that the evidence would have been unfavorable to the defendant.

I. The Law Supports a Ruling That Mitek Is Entitled To An Adverse Inference Instruction

The First Circuit has two prerequisites for showing entitlement to an adverse inference instruction – (a) knowledge about the litigation and (b) knowledge about the potential relevance of the destroyed information to the litigation.[1] This Circuit has held "with some regularity" that a jury may infer from a party's "obliteration of a document relevant to a litigated issue that the contents of the document were unfavorable to that party." *Testa,* 144 F.3d at 177; *Blinzler,* 81 F.3d at 1159. "This permissive negative inference springs from the common sense notion that a party who destroys a document (or permits it to be destroyed) when facing litigation, knowing the document's relevancy to issues in the case, may well do so out of a sense that the document's contents hurt his position." *Testa,* 144 F.3d at 177.

[1] *Testa v. Wal-Mart Stores, Inc.,* 144 F.3d 173, 177 (1st Cir. 1998) (*citing Blinzler v. Marriott Int'l, Inc.*, 81 F.3d 1148, 1158 (1st Cir. 1996); *Anderson v. Cryovac, Inc.*, 862 F.2d 910, 925 (1st Cir. 1988); *Nation-Wide Check Corp. v. Forest Hills Distributors, Inc.*, 692 F.2d 214, 217-18 (1st Cir. 1982)).

A. Defendants' Experts Conduct

Mitek satisfied the prerequisites for an adverse inference instruction. The record demonstrates that both Dr. Gitis and Dr. Burks knew:

(a) about the litigation because they were specifically retained in this matter to provide Rule 26 expert reports and testimony; and

(b) that their testing of so-called "coated" and "uncoated" sutures was relevant to the litigation because they were retained to opine about the effect of FiberWire's coating on the novel and basic characteristics of the invention.

1. Dr. Gitis' Test Data and Results Were Not Preserved

Dr. Gitis performed a series of tests that supposedly related to the surface friction properties of FiberWire so Defendants could purportedly show that FiberWire's coating materially affected the novel and basic characteristics of the Hunter 446 Patent's invention. Among the tests Dr. Gitis carried out, he performed two "tissue drag" tests, a "clamp" test and a "needle" test (Mitek Trial Br. Ex. 9 at 12) (Ex. 1). Dr. Gitis reported the results of the "clamp" test but did not report the results from his "needle" test in his expert report; nor were the data from the "needle" test produced, as he testified that he destroyed those data (Mitek Trial Br. Ex. 10 at 271:15-272:9) (Ex. 2). Dr. Gitis' explanation for destroying the "needle" test data is that the results were supposedly the same as the "clamp" test results (*id.* at 271:6-9; 271:23-272:5). But according to his testimony, he could not have compared them because he overwrote the data from the "needle" test with the data from the "clamp" test (*id.* at 271:10-272:9). Because Dr. Gitis destroyed the "needle" test data and results, Mitek did not have the opportunity to consider whether Dr. Gitis' "needle" test conflicted with his other tests or whether those results supported Mitek's position rather than Defendants' position. Mitek is thus entitled to an adverse inference that the data were unfavorable to Arthrex's position.

2. Dr. Burks' Communications With Defendants' Counsel Were Not Preserved

Dr. Burks was provided with samples of so-called "coated" and "uncoated" FiberWire sutures so that he could perform a tactile feel analysis of the samples. After the analysis, Dr. Burks sent an email to Defendants' counsel discussing his results (Mitek Trial Br. Ex.11 at 74:24-75:3) (Ex. 3). But neither Dr. Burks nor Arthrex ever produced that email (*id.* at 74:24-75:5), despite it being responsive to document requests and a subpoena served on Dr. Burks.

Under the circumstances, Mitek respectfully requests a ruling that the Court instruct the jury that it should draw an adverse inference from Arthrex's destruction of evidence. *Testa*, 144 F.3d at 178 (affirming negative inference instruction where there was sufficient prove that offender had notice of both a potential lawsuit and the destroyed documents relevance to the suit).

II. CONCLUSION

Based on the defendants' failure to preserve evidence, Mitek requests an instruction that the jury may infer that the destroyed information was unfavorable to Arthrex.

Dated: August 6, 2007

DEPUY MITEK, INC.,
By its attorneys,

_/s/ Erich M. Falke_____________
Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
2929 Arch Street, 12th Floor
Cira Centre
Philadelphia, PA 19104
(215) 568-3100

Daniel J. Gleason (BBO #194900)

Heather Repicky (BBO #663347)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604
617-439-2000

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

DePuy Mitek Bench Memorandum Regarding Arthrex's Spoliation of Evidence

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date *via* the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro LLP
1825 Eye Street, NW
Washington, DC 20006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: August 6, 2007

/s/ Erich M. Falke
Erich M. Falke

EXHIBIT 9

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

"Confidential-Non-Patent-Prosecution Counsel Only"

March 23, 2006

Comparative Suture Testing

1. Introduction

Center for Tribology, Inc., abbreviated CETR, is a privately held California corporation, located in the heart of Silicon Valley in the city of Campbell, county of Santa Clara. It was founded by Dr. Norm Gitis in November 1993 and incorporated in California in October 1994. Its main charter has been helping major corporations and universities all over the world in research, development and failure analysis of materials, coatings and lubricants for the computer peripherals (20% of revenues), semiconductor (20% of revenues), biomedical (15% of revenues) and other industries (20% of revenues), as well as for fundamental academic studies (25% of revenues). A list of its customers is attached in Appendix 1.

CETR is a multi-million-dollars corporation with two lines of business, design & sales of mechanical & tribology test equipment (90% of revenues) and testing & consulting services on mechanical & tribological properties of materials and devices (10% of revenues).

CETR is one of the largest and leading producers of mechanical and tribology testers in the world. In particular, it has supplied them to leading domestic suture manufacturers, such as Ethicon, Inc. of Johnson & Johnson and United States Surgical of Tyco Healthcare, as well as such well-known corporations as Gillette, Guidant, Medtronic, Schick, Procter & Gamble, Unilever, etc.

Dr. Norm Gitis, President of CETR, is a well-known expert on tribology testing with 30 years of experience in friction, wear and fatigue testing of materials and devices. His resume is attached in Appendices 2a – 2c.

CETR has successfully provided highest quality laboratory test data in several lawsuits, including most recently between Alaska Airlines, Boeing, and families of victims of the Alaska flight 261 (related to the reliability of a jack-screw/nut assembly on Boeing airplanes and a plane crash in 2000), between American Airlines, Sabre Travel Network and Western Digital (related to the reliability of computer disk drives used for travel reservations), and between Boston Scientific and US Justice Department (related to the quality of implantable cardiovascular stents). It has been charging $ 2,500 per day or $ 10,000 per week for its regular lab testing services and double prices for priority urgent services.

Dr. Gitis has successfully testified in several depositions, most recently in a lawsuit between Seagate Technology and Cornice, Inc. related to the intellectual property on the mechanical design of portable magnetic disk drives. He has also given successful testimonies at several trials, most recently in lawsuits between Swiss Air, Interactive Flight Technology, Avnet and other parties (related to the reliability of computerized on-demand in-flight video system and a crash of Swiss flight 111) in the court of Arizona and between Iomega and Nomai (related to the reliability of Zip high-density floppy-drives) in the Higher Court of

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

United Kingdom, courts of Amsterdam, Dusseldorf, etc. He has been charging $ 350 per hour plus trip expenses for his consulting and expert witnessing services.

2. Project Goal

At the end of February 2006 CETR was requested by a law firm of Dickstein, Shapiro, Morin & Oshinsky, LLP (located at 2101 L Street NW, Washington, DC 20037) and its technical expert Dr. Debi Mukherjee to perform comparative mechanical and tribological testing of two types of FiberWire surgical sutures, coated and uncoated.

They requested the following parameters be tested: i) pliability/bendability, ii) knot tie-down/run-down, iii) knot security, iv) chatter, v) coefficient of friction, vi) tissue drag, vii) microscopy examination.

We have been told that this project is related to a patent infringement lawsuit between DePuy Mitek, a Johnson & Johnson company and Arthrex, the latter being the client of this law firm. Any details of the lawsuit have been neither requested by CETR nor provided to CETR.

3. Suture Samples

In the beginning of March 2006 CETR received via FedEx two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated. Each spool contained approximately 20 m of suture. Two CETR employees Dr. Norm Gitis and Mr. Michael Vinogradov examined the spools of sutures and found them to be apparently brand new.

Upon agreement with the law firm and Dr. Mukherjee, before conducting any tests, we sent both the spools of sutures for ETO sterilization to a reputable sterilization lab Sterile Systems, Division of Medtronic Inc. (located at 520 Watson S.W., Grand Rapids, MI 49504). The same Mr. Michael Vinogradov handled the sutures before the shipment and after receiving them back. Both shipments to and from Sterile Systems were performed via FedEx.

Upon receiving back the sterilized sutures, we handled them only and always with clean-room gloves. We cut about 3 m of each of the coated and uncoated sutures and shipped by FedEx to a surgeon expert, as requested by the law firm. The rest of the spools were utilized in our tests described below.

4. Set Of Test Procedures

Based on the CETR experience with its suture-tester customers Ethicon (New Jersey) and US Surgical (Connecticut), its general expertise in mechanical & tribology testing and familiarity with the relevant literature, as well as on the suggestions of the law firm, CETR has proposed a suit of test procedures for the requested tests, that was approved by the law firm's technical expert Dr. Mukherjee and then performed by CETR in mid-March, 2006.

5. Pliability Tests

The experimental procedure, based on the published work of Rodeheaver et al. [1], was as follows.

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

Suture of 50 mm in length and 0.65 mm in diameter was clamped between the force sensor and the lower specimen holder as shown in fig. 1. The suture was preloaded with a tension of 0.5 Kg (5 N). Preloaded suture was then pulled at a force, uniformly increasing at the rate of 0.33 kg/sec. Force and elongation data were continuously monitored and recorded. The strain in the suture was calculated as the ratio of elongation to the initial length of 50 mm. The force-strain plots like the one shown in fig. 2 were made and their slopes were measured. Modulus of elasticity (E) was then calculated by dividing the slope with the cross-sectional area of the suture. Area moment of inertia (I) was calculated assuming a circular cross-sectional area. Stiffness was then calculated as a product of the modulus of elasticity and the area moment of inertia of the suture:

$$K = E*I$$

where
K – Stiffness,
E - Modulus of elasticity - Slope of the force-strain graph / cross-sectional area of the suture

I - Area moment of inertia - $\frac{\pi * D^4}{64}$ where D - diameter of the suture (0.65 mm)

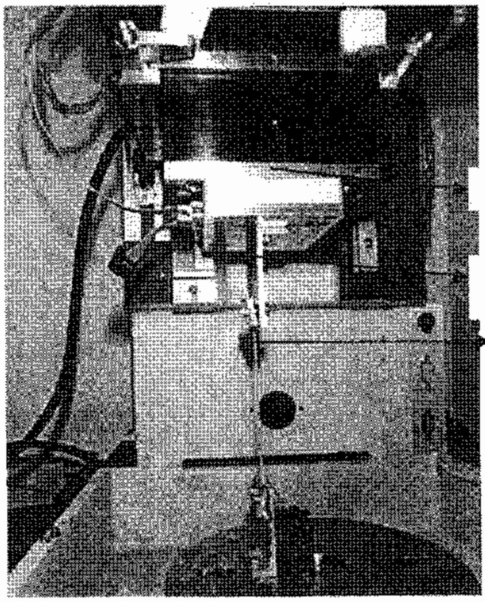


Figure 1. Test set up for pliability testing

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

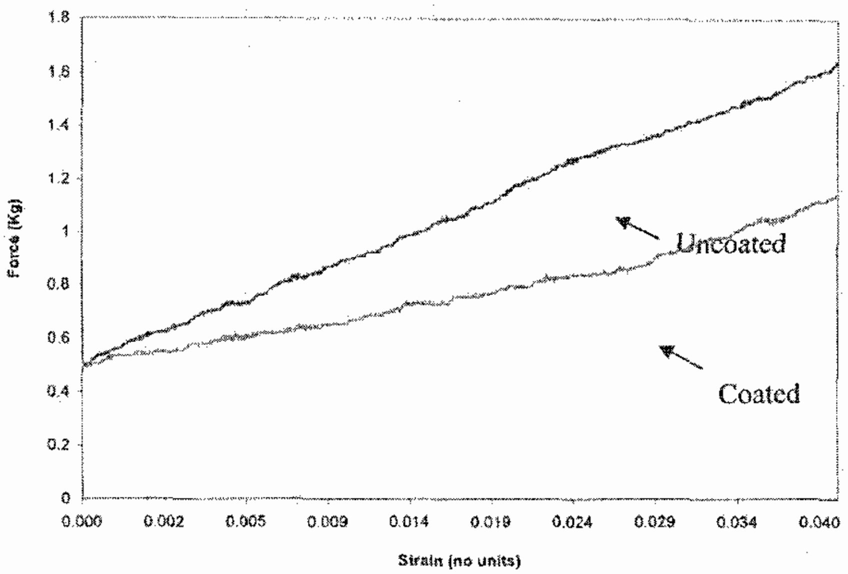


Figure 2. Typical force-strain data for coated and uncoated sutures during pliability tests

The stiffness values as calculated in the above described procedure are summarized in the Table 1.

Table 1. Pliability test data

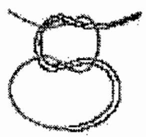
Exp #	Stiffness (*E10-7 kg x m^2)	
	Coated Suture	Uncoated Suture
1	6.51	10.07
2	7.53	9.73
3	5.98	11.3
4	6.44	11.3
5	4.95	8.29
6	5.67	8.00
7	5.98	9.61
8	5.41	10.6
Average	6.06 ± 1.29	9.93 ± 1.66

The stiffness of the coated sutures was found to be lower than that of the uncoated ones. This suggests that the coated sutures have higher pliability and thus facilitate better handling during surgical use. The test data corresponds well to the data reported by Rodeheaver et al [1].

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

6. Knot Slippage Strength Tests

The knot slippage strength tests were conducted to evaluate the knot security offered by each suture. The experimental procedure was carried out based on previous works in the literature [2, 3]. A loop of the suture was formed by tying a 'square knot' as shown in fig 3 [4] around a cylinder of 2.5 cm diameter. The loop thus formed was slipped off the cylinder and soaked in 0.9% weight/volume sodium chloride for 1 minute to closely represent the real environment. The soaked loop was then placed around 2 parallel brass rods of 5 mm diameter, which were mounted onto the UMT-2 machine as shown in fig. 4. A pre-load of 1 N was applied to the loop. The parallel rods were then pulled apart at a constant velocity of 1 mm/sec. The force was continuously monitored and recorded during the experiment. The force when the knot starts slipping was noted as the knot slippage force. The rods continued to be pulled apart until either the knot got untied or a slippage of 3 mm occurred. The force at that instant gives the knot failure force.



Square

Figure. 3 'Square knot' used for the knot slippage strength tets

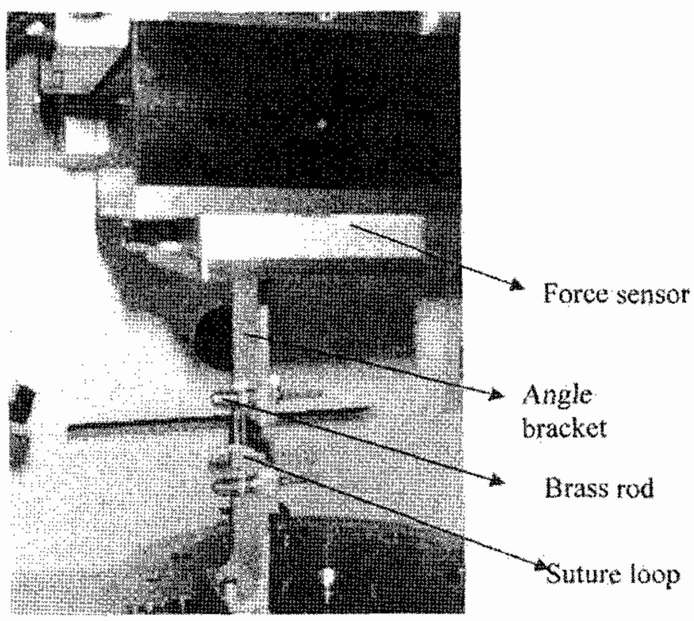


Figure 4. Test set up for knot slippage strength measurement

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

The typical force response curves as recorded during the experiments are presented in the fig. 5 below.

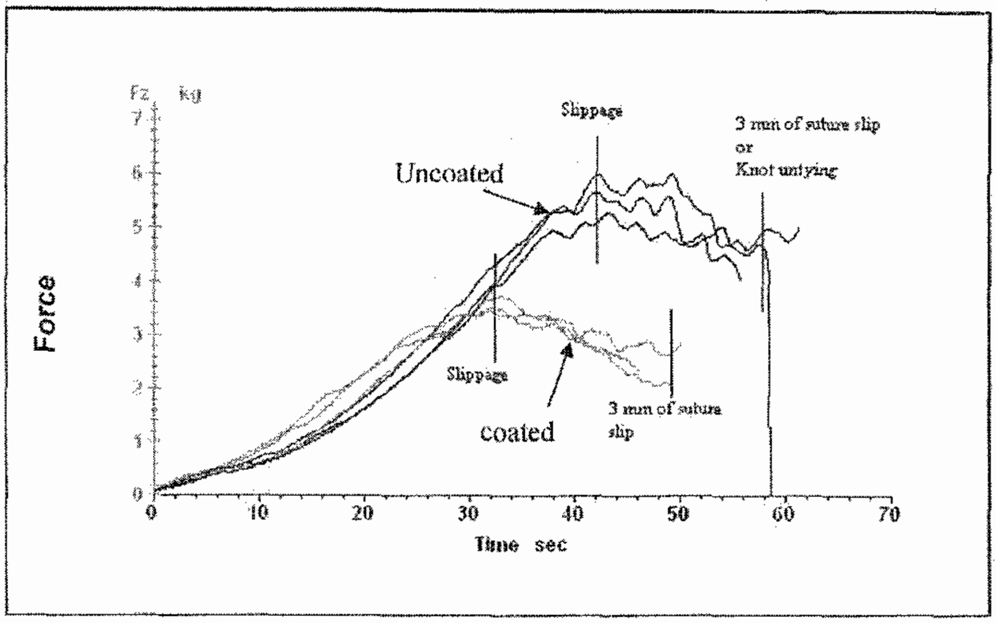


Figure 5. Typical data for force at slippage and knot failure for coated and uncoated sutures

The knot strength values as determined from the curves are summarized in the Table 2 below.

Table 2. Knot strength data for coated and uncoated sutures

Exp #	Knot strength (kg)			
	at slippage		at knot failure	
	Coated	Uncoated	Coated	Uncoated
1	3.52	5.33	3.06	4.09
2	2.36	4.97	2.03	4.09
3	3.46	4.80	3.15	2.42
4	4.25	6.04	2.07	2.98
5	3.74	4.70	2.40	3.53
6	2.43	5.36	2.77	4.79
7	3.47	4.86	2.09	3.45
8	3.27	5.10	2.64	3.90
Average	3.31± 0.95	5.14 ± 0.67	2.52 ± 0.56	3.36 ± 1.19

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

From the above data it can be concluded that the knots tied using the coated sutures slipped and failed at lower forces when compared to the knots tied using uncoated sutures. The experimental data compare well with the data reported in the previous works [2, 3].

7. Knot Run-down Tests

The suture was tied with a 'half hitch knot' as shown in fig. 6 [4] around a supplemental cylinder with a 2.5 cm diameter. The loop thus formed was then slipped off the supplemental cylinder and placed on the lower brass rod of the UMT-2 testing machine. The knot was then subjected to running-down by pulling at a constant speed of 1.5 mm/sec on the longer free end in the testing machine as shown in fig. 7. The test procedure was based on the description provided in the literature [5]. The pulling force was continuously recorded as the knot traveled down the suture. Chatter or variation in knot run-down force was also noted.

Figure 6. Half-hitch tied for the knot run-down tests

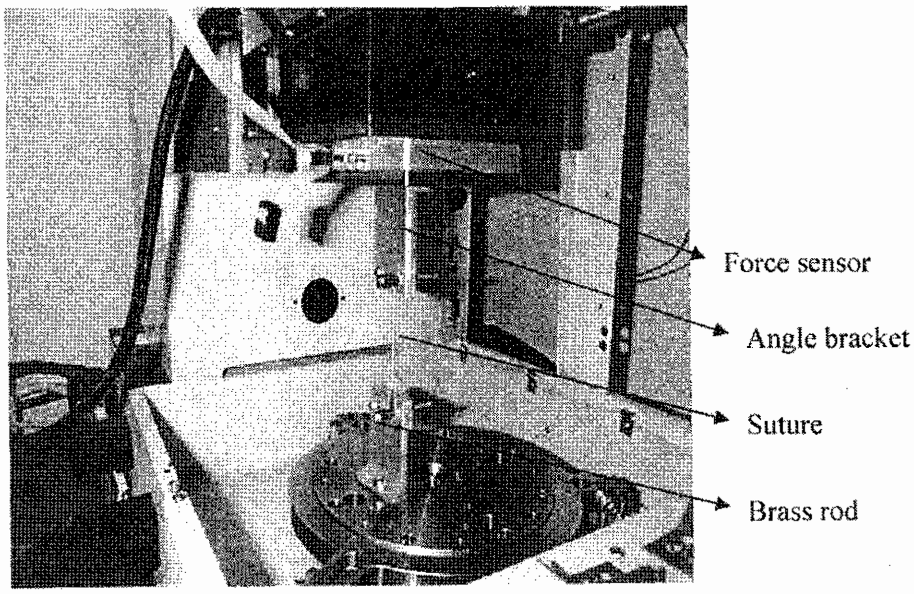


Figure 7. Test set up for the knot run-down test

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

The typical pulling force data from the tests performed on coated and uncoated sutures plotted versus time is shown in fig. 8 below:

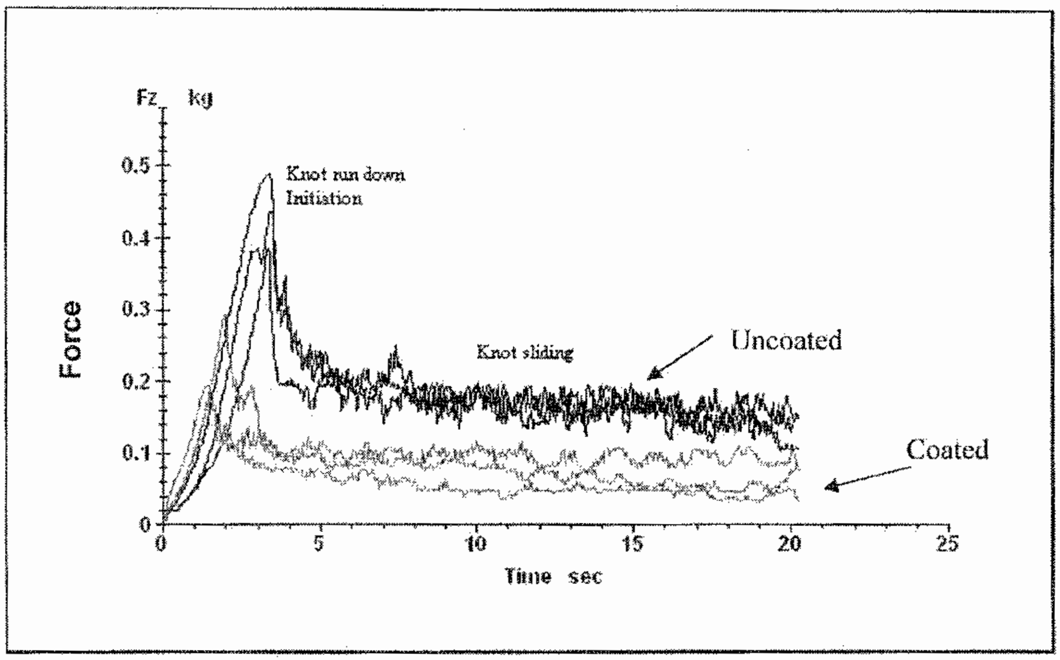


Figure 8. Force versus time for coated and uncoated sutures during knot run-down experiments

The force when the knot begins to slide over the suture was noted from the pulling force data. This gives the run-down force. The run-down force values as measured from the test data are tabulated in the Table. 3 below:

Table 3. Knot run-down test data

Exp #	Run-down force (kg)	
	Coated suture	Uncoated suture
1	0.28	0.39
2	0.20	0.54
3	0.26	0.42
4	0.22	0.49
6	0.18	0.44
7	0.19	0.28
8	0.21	0.26
average	0.22 ± 0.05	0.40 ± 0.14

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

As can be seen from the above result, the coated sutures had lower run-down force when compared to the uncoated sutures.

8. Friction tests

The schematic of suture-on-suture testing set-up is shown in the fig. 9 below.

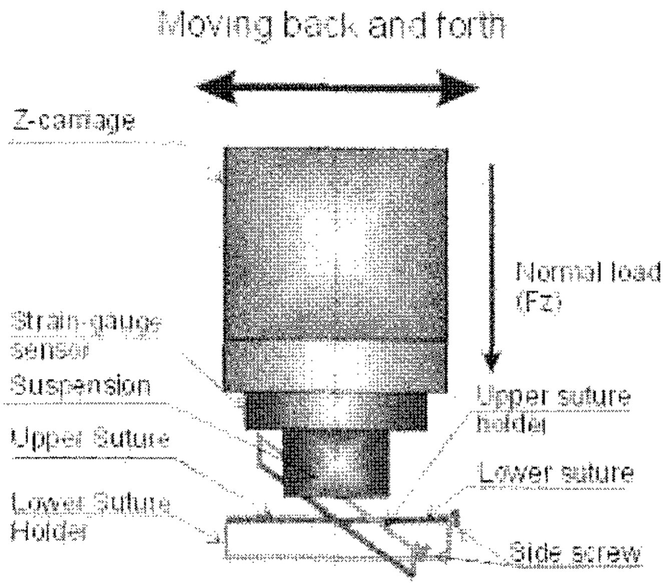


Figure 9. Test schematic for measuring suture-on-suture friction

A sample of suture was mounted and tensioned on the upper sample holder and another sample of the same suture was mounted and tensioned on the lower sample holder. The tension of both the sutures was adjusted using side screws to ensure constant tension for each suture, as shown in fig. 10. The upper suture was moved on the lower one back and forth with a reciprocating length of 3 mm at a frequency of 0.5 Hz under a constant normal load of 2 N (0.2 kg) for 200 seconds. A close-loop feedback loading mechanism ensured a constant normal force.

Both the applied vertical load and friction (shear) response force were continuously monitored and recorded during the tests.

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

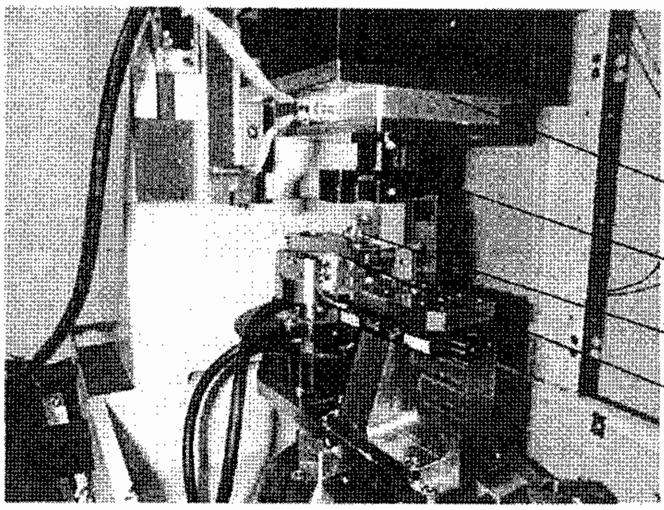


Figure 10. Set up of suture-on-suture friction tests

The coefficient of friction curves as recorded during the reciprocating tests are presented in fig. 11 below. The uncoated sutures had higher average coefficient of friction. The numerical data from the tests are noted and summarized in table. 4

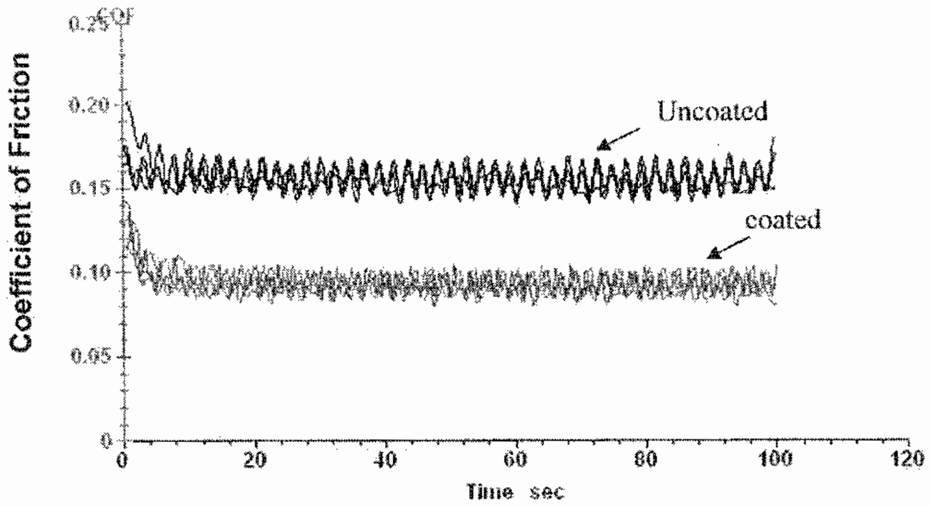


Figure 11. Typical Coefficient of Friction curves for Coated and Uncoated Sutures

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

Table 4: Average coefficient of friction data from suture-on-suture tests

Exp #	Coefficient of Friction	
	Coated suture	Uncoated suture
1	0.09	0.15
2	0.10	0.17
3	0.08	0.16
4	0.10	0.16
5	0.09	0.16
6	0.09	0.16
7	0.09	0.17
8	0.10	0.17
Average	0.09 ± 0.01	0.16 ± 0.01

From the above results, it can be seen that the coated sutures have lower coefficient of friction when compared to the uncoated sutures. This result correlates well with the run-down force data in the previous section. The average coefficient of friction data is similar to the previous data [1, 6].

9. Chatter Data

Chatter is termed as the variation in friction during knot run-down and/or reciprocating friction tests. These variations are due to stick-slip process between the interacting suture surfaces when the knot is tied-down [5]. The difference between the maximum and the minimum friction coefficients, or amplitude of frictional auto-oscillations, is the measure of the chatter. Chatter data measured from both the knot run-down and the suture-on-suture friction tests are summarized in the table 5 below.

Table 5: Chatter data from knot run-down and suture-on-suture tests

Test #	Chatter data	
	Coated suture	Uncoated suture
1	0.009	0.013
2	0.009	0.017
3	0.008	0.013
4	0.008	0.013
5	0.010	0.012
6	0.012	0.011
7	0.008	0.014
8	0.010	0.019
average	0.009 ± 0.001	0.014 ± 0.003

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

The chatter was higher for the uncoated sutures when compared to the coated ones. This result strengthens the conclusion from the previous results that coated sutures provide greater ease of handling during surgical use.

10. Tissue Drag Tests

The frictional force encountered during the passage of the suture through a tissue is termed as tissue drag. A 20-mm length of suture was pulled through a piece of leather at a constant rate of 1 mm/sec, while continuously recording the pulling force. The test procedure is based on the description provided in the previous works [7]. The leather piece was held in position using fixtures as shown in fig. 12. Two types of tests were performed: dragging the suture through the hole made with a needle and dragging the suture between two tightly clamped pieces of leather. In both cases, the upper end of the suture was attached to the UMT upper bracket providing the well-controlled motorized dragging action. The average drag force measured in both types of experiments was identical.

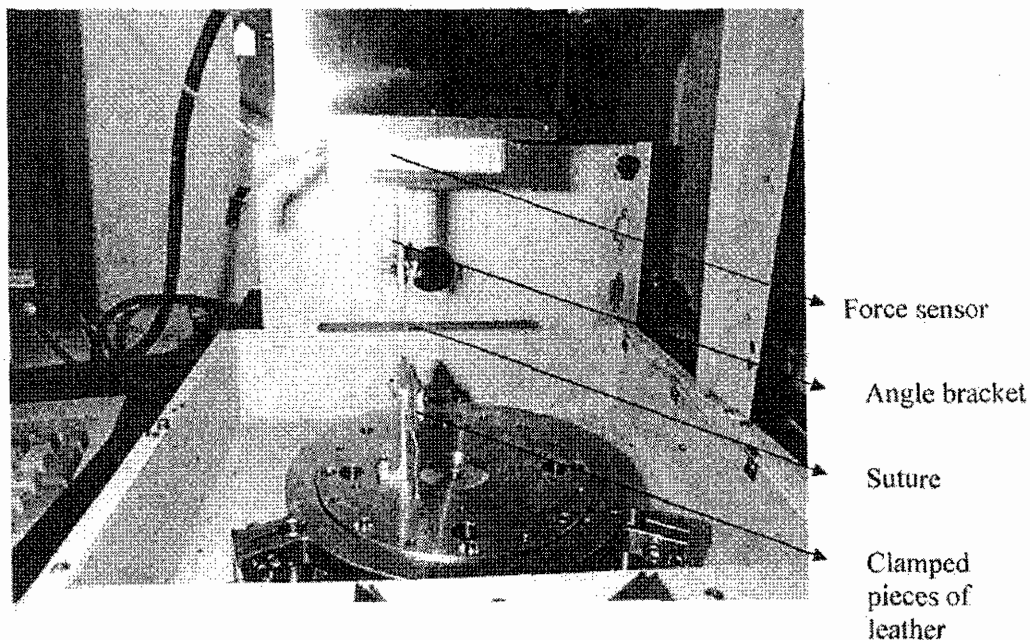


Figure 12. Test set up for the tissue drag test

Fig. 13 presents the force required to pull the coated and uncoated sutures. The highest force recorded gives a measure of the static drag force that was necessary to overcome in order to initiate the suture motion through the leather. The dynamic drag force was measured during the motion of the suture. The average static and dynamic drag forces are summarized in Table 6. The data are comparable to the previously reported results [1].

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

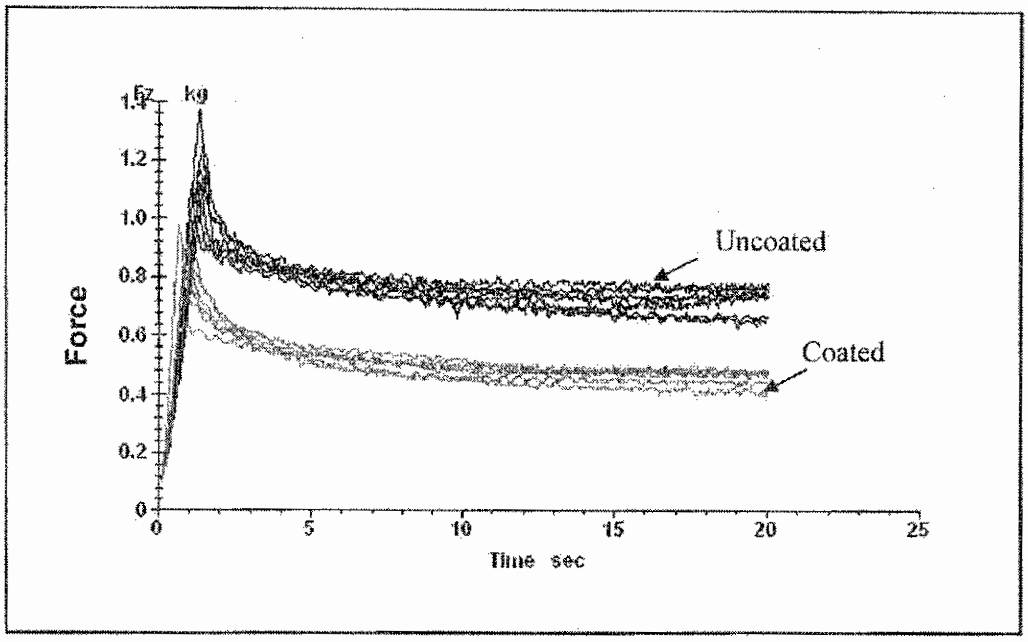


Figure 13. Typical force curves for coated and uncoated sutures.

Table 6. Drag force from the tissue drag tests

Exp #	Drag force (kg)			
	Static		Dynamic	
	Coated suture	Uncoated suture	Coated suture	Uncoated suture
1	1.10	1.15	0.55	0.74
2	0.85	1.20	0.52	0.78
3	0.71	1.19	0.41	0.84
4	0.68	1.39	0.46	0.91
5	0.97	1.10	0.46	0.85
6	1.11	1.19	0.58	0.64
7	0.90	1.13	0.51	0.77
8	0.92	1.13	0.50	0.72
Average	0.91 ± 0.20	1.18 ± 0.15	0.50 ± 0.11	0.78 ± 0.14

11. Microscopy Data

We have attempted to stud y the structure of the sutures with a digital optical microscope, attached to the same UMT tester, but the structure was undistinguishable. So, we utilized

CETR
CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

laboratory imaging services of a reputable local analytical lab AMER in Sunnyvale, California. Dr. Gitis brought samples of the uncoated and coated sutures to AMER and was present there all the time while their lab engineer Tony Lin performed SEM (scanning electron microscopy) imaging.

The obtained images are presented below in figures 14 and 15.

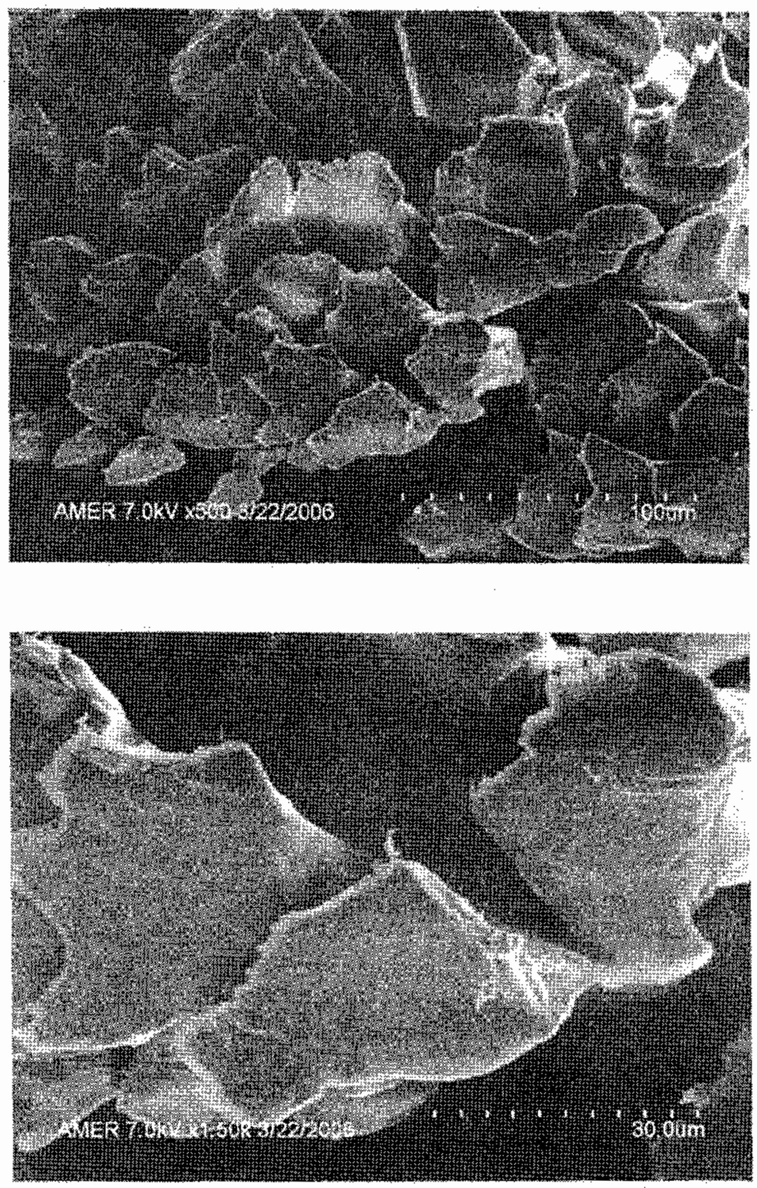


Figure 14. SEM Photos of the Coated Suture

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

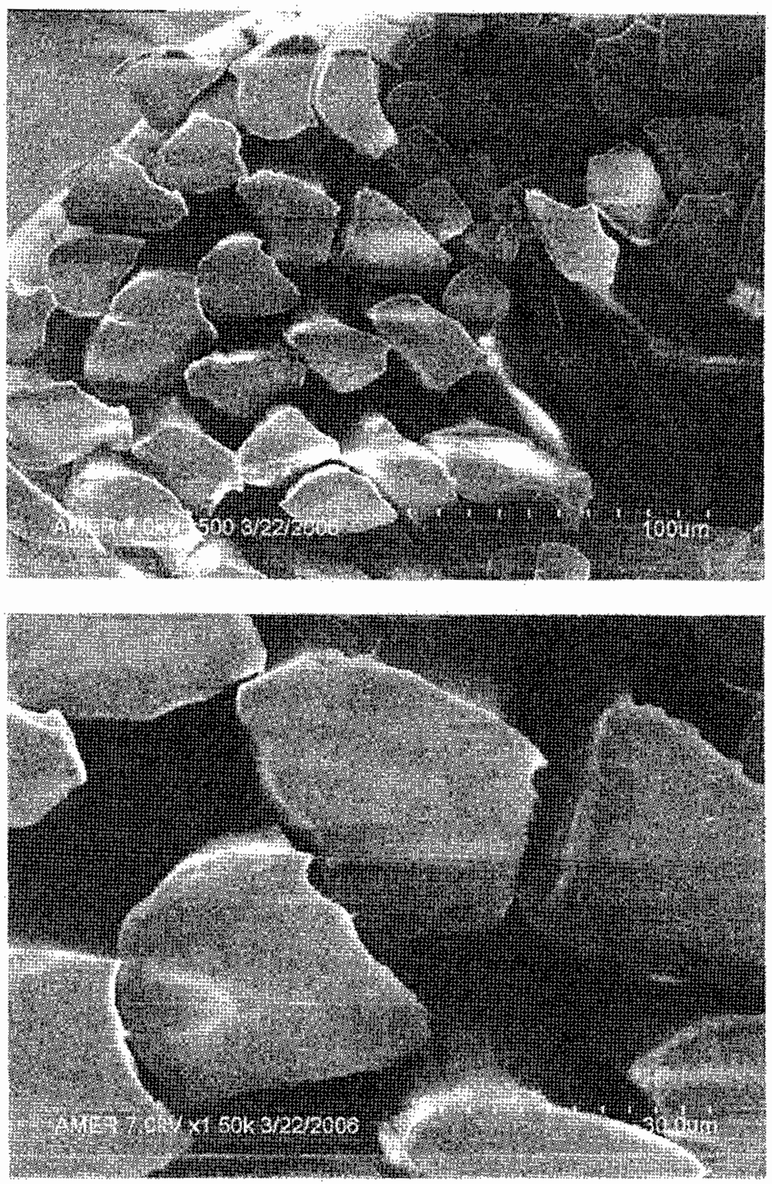


Figure 15. SEM Photos of Uncoated Sutures

12. Statistical Significance of Test Data

We used a common t-distribution statistical analysis, assuming the test data to be normally distributed The t-analysis assesses whether the means of two data groups are statistically

CETR
CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

different from each other. Then the test statistic (t-value) is calculated as [8, 9]:

$$t = \frac{Xu - X_c}{\sqrt{\frac{Vc}{Nc} + \frac{Vu}{Nu}}}$$

where X_c and V_c - mean and variance, correspondingly, of data for coated suture,
X_u and V_u - mean and variance, correspondingly, of data for uncoated suture,
N_c and N_u - number of tests for coated and uncoated sutures, correspondingly (N = 8).

The calculated t-values for all our test data are presented in Table 7 below.

Table 7. Comparison of t-values for data significance

Test	Coated		Uncoated		Experimental "t"-value	"T" threshold
	Xc	Vc	Xu	Vu	t	T
Stiffness	6.06 E-6	6.17 E -13	9.93 E-6	1.6 E -12	7.35	1.76
Slippage Strength	3.31	0.41	5.14	0.19	6.72	1.76
Untie Strength	2.52	0.2	3.66	0.54	3.72	1.76
Run-down Force	0.22	0.001	0.4	0.01	4.62	1.76
Friction	0.09	3.58 E -5	0.16	5.66 E -5	20.27	1.76
Chatter	0.009	1.58 E -6	0.014	6.91 E -6	4.63	1.76
Static drag	0.91	0.025	1.18	0.008	4.29	1.76
Dynamic drag	0.5	0.003	0.78	0.007	7.91	1.76

To make a conclusion that the difference between groups of data is statistically significant, the t-value should be larger when compared to a T-threshold calculated based on the degrees of freedom of the distribution and an error level. Degrees of freedom is calculated as [8]: DoF =

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

Nc + Nu – 2 = 14. An error level of 0.05 (5%) is most commonly used. Based on the DoF and error level, the T-threshold is found from a standard t-distribution table [8, 9] to be T = 1.76.

As seen from the Table 7, the computed t-values of test data are much greater than the threshold T level, which allows us to conclude that the observed differences between coated and uncoated sutures are statistically significant.

Norm Gitis

Dr. Norm Gitis
President, Center for Tribology, Inc.
Chairman, STLE Technical Committee on Tribotesting

References:

1. George Rodeheaver et al, Journal of Surgical Research 35, 525-530 (1983)
2. Arthroscopy: The Journal of Arthroscopic and Related Surgery Vol. 16, No 2, (2000), pp 202-207
3. Schubert et al, American Journal of Obstetrics and Gynecology, Vol.187, (6), (2002), 1439
4. www.ukvet.co.uk/ukvet/articles/ surgery_suture%20patterns.pdf
5. Perciaccante et al, US patent No: 4,047,533, September 1977
6. http://www.cetr.com/Brochures/Mechanical_Tester_for_Bio-Medical_Materials_and_Devices.htm
7. Rao Bezwada et al, Biomaterials 16 (1995) 1141-1148
8. http://www.socialresearchmethods.net/kb/stat_t.htm
9. Douglas Montgomery, Design and Analysis of Experiments, John Wiley & sons, Inc.

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF MASSACHUSETTS

------------------------------x

DEPUY MITEK INC., a Massachusetts Corporation, :

Plaintiff, :

vs. : Civil Action No.

ARTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom, : 04-12457

Defendants. :

------------------------------x

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by counsel for the Plaintiff, pursuant to notice, commencing at 8:15 a.m., at the law offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, D.C., before Dawn A. Jaques, Certified Shorthand Reporter and Notary Public in and for the District of Columbia, when were present on behalf of the respective parties:

A. Yes.
Q. And on the graph that's on the first page of Exhibit 393, there is eight graphs present, eight lines presented. Do you see that?
A. Yes.
Q. And they're labeled Coated 1 through 8. Do you see that?
A. Yes.
Q. Do the Coated 1 through 8 that are in there correspond to the Experiment No. 1 through 8 that are in the pliability test data chart?
A. Yes.
Q. Okay. Now, if we look at 394, the first column is FZ in kilograms. Do you see that?
A. Yes.
Q. What force is that?
A. Vertical force.
Q. That's the force that's being applied to the specimen placed under tension?
A. Yes.
Q. The second column is time and seconds; is that right?
A. Yes.
Q. The third column is Z in millimeters, right?

A. That's correct.
Q. What is Z?
A. Displacement in millimeters.
Q. Vertical displacement, so it's how much the specimen is being stretched, right?
A. Yes.
Q. Okay. The fourth column is ZABS, Z-A-B-S; is that right?
A. Yes.
Q. What is ZABS?
A. I don't remember.
Q. Don't know?
A. I don't remember.
Q. Okay. The fifth column is Strain. Do you see that?
A. Yes.
Q. What is that?
A. Strain is the ratio of the relative displacement over the initial position.
Q. So this strain --
A. Elongation over -- strain is defined as relative elongation, elongation over the length.
Q. So is it correct that the strain is the distance measured with the Z parameter divided by the length?

A. Yes.
Q. So at the first instance, the length was measured to be 50 millimeters. That was the gauge length you used, right?
A. Yes.
Q. So the time -- at the first entry, let's say, the strain --
A. No change.
Q. There was no change.
A. Zero change. Zero divided by any number gives zero.
Q. Zero. Second entry says -- for the Z column is 24.8735, right?
A. Yeah.
Q. So the strain then would be 24.8735 divided by 50, plus 24.8735 for that data point?
A. Yeah.
Q. For the next data point, it would be 24 point -- the strain would be 24.8735 divided by 50, plus 24.8735?
A. Yes.
Q. So it keeps on doing that?
A. Yes, all the time.
Q. Okay. And you said in your task, if you go back to your report on page 3 at the top, you

said that suture was tested -- was preloaded with a tension of .5 kilograms, 5 newtons, right?
A. Yes.
Q. How did you arrive at that parameter?
A. Why did we choose this parameter, because we followed the literature recommendations by Dr. Rodeheaver and by Ethicon.
Q. Did one of those documents actually specify a 5 newton preload?
A. I think so.
Q. What happens if they didn't?
A. I would be surprised.
Q. If they didn't, would you know where it came from?
A. I am under the impression that it came from the literature.
(DePuy Mitek Exhibit No. 395 was marked for identification.)
BY MR. BONELLA:
Q. Let me show you what's been marked as DePuy Mitek Exhibit 395. It's Dr. Mukherjee's response of expert report. I'd like to ask you to turn to Exhibit -- I'm going to turn to Exhibit 13.
Exhibit 13 to that report is --

holders or these sensors or whatever, but I cannot speculate what causes the difference between uncoated and coated, because as we discussed, I only know labels, coated and uncoated, so I cannot speculate what causes their differences. Erich, you need a new printer.

(DePuy Mitek Exhibit No. 404 was marked for identification.)

BY MR. BONELLA:

Q I'm going to show you the next exhibit, Exhibit 404, which I believe is the knot strength test data and curves for the uncoated samples. I ask you to verify that.

A Uncoated, yes.

MR. TAMBURO: You want him to look through that 8 inches worth of documents?

BY MR. BONELLA:

Q Do you know? Can you just look at the --

A Yeah, I see it. It's uncoated, yeah.

Q Is that the data for the non-slippage test?

A Yes.

(DePuy Mitek Exhibit No. 405 was marked for identification.)

BY MR. BONELLA:

Q Is Exhibit 405 the graphs and data for the coated non-slippage test?

A Yes.

Q Okay. Let's take, for example, the coated. Turn to the first part. This is where you were putting the preload on, right? The first part of the data should be where you put the preload on; is that right?

A Yes.

Q Okay. There is, for example, sample 1 we'll use an example, there's five columns, right?

A Yes.

Q First column is F sub X. What is that?

A FX is horizontal force in X direction.

Q Force in X direction. If we're looking at Figure 7, your set-up, which is the X direction?

A X direction is parallel to the paper.

Q Parallel to the paper. That's not specific.

A I'm sorry, what are you looking --

Q Figure 7, your test set-up. That's right, you got it.

A No, you said Figure 7.

Q Oh, do I have the wrong one? I'm sorry, I have the wrong one. Figure 4.

Okay, so where was the X direction for Figure 4?

A Left-right direction within the plane of the paper.

Q I'm having a hard time understanding because there's two planes to the paper. Well, there's one plane, but there's two directions. There's a --

A I'm sorry, do you see -- how to define X. If you see a force sensor, it has some kind of lengths, so X is along the length of the force sensor.

Q Okay. So would the force X be into the diameter of the brass rod?

A Yes.

Q Next column is F sub Z. What is that?

A It's a vertical force.

Q That's the tension force that you're measuring?

A The tension force.

Q That you measure to get the results?

A Yes.

Q T is time and seconds, right?

A Yes.

Q Z is what?

A Z is vertical displacement.

Q Okay. So that's what you're looking at to determine slippage?

A Yes.

Q And the last column is F sub F. Do you see that?

A Yes.

Q Is that the force in the Y direction?

A Actually, that's friction coefficient.

Q That's friction coefficient?

A Yeah.

Q In kilograms?

A Okay, I am confused.

Q Weren't you trying to keep the forces in the X direction and the Y direction the same?

A No, FY would say FY. So I'm sorry, I confused. I don't remember. I can find it out and let you know. I don't remember specifically.

Q You don't know what FF is? Look FX and FF columns, if you look at those --

A Yes. They seem to be of certainly equal --

Q Except for this sample they're not.

labeled brass rod is?
A That's correct.
Q The knot was then subject to running down by pulling at a constant speed of one and-a-half millimeters per second on the longer free end in the testing machine as shown in Figure 7, right?
A Yes. The free end was like upper end, and the loop was like the lower end of the suture on Figure 7.
Q The loop is around the rod, right?
A Yes.
Q And then there's two ends?
A Right.
Q One was -- and you pulled on one end?
A Yeah, the longer end.
Q Okay. And the longer end, how did you attach that to something to pull on it?
A How we attached it to the -- to the upper specimen, with the same angle bracket as was shown in pliability test and knot strength test.
Q It doesn't show it.
A As you said, you can call it bolt and nut.
Q I'm sorry.

A As you said previously, you can call it bolt and nut, how we clamp the suture.
Q I don't understand what you just said.
A Okay.
Q I don't understand what you're saying.
A Earlier when I described our clamp to clamp the suture, you asked me whether you can call it bolt and nut, and I said yes.
Q Okay. I see in the Figure 7, test set-up for the knot run-down, there's a brass rod in the upper fixture.
A Yes.
Q What was that used for? Looks like the suture is looped around it, no?
A Yes. Maybe it's wrong photo. It's photo from Figure 4. Maybe it's the right photo for the upper attachment is the same as in Figure 1.
Q Wait a minute, I'm confused now. Are you saying Figure 7 may not be the knot run-down test?
A Figure 7 is -- no, no. It's correct. Figure 7 is a knot run-down test. The loop was formed on the separate supplemental cylinder, was then transferred on the brass -- on the lower

brass rod.
Q Yes.
A And then the free -- longer free end was just attached to the upper rod.
Q Attached to the upper brass rod?
A Yes.
Q How was it attached to the upper brass rod?
A I don't remember.
Q Was it tied in a knot?
A I don't remember. Most likely it was tied in a knot.
Q How about the lower -- how about the other end, what happened to the other end of the suture? What did you do with that?
A I believe it was cut like in all the referenced literature.
Q What do you mean cut? There's two ends of the suture that are in the half hitch, and one you said goes up --
A The longer ones, the free one, goes on the upper rod.
Q Okay. What happens to the lower one? What happens to the other end?
A I don't remember. We didn't describe

here, and I don't remember.
Q Well, how is the knot running down? I mean, what's holding the other end? Something's got to hold the other end, right --
A Right.
Q -- if it's a run-down test.
A Right. Sorry, I don't remember.
Q So you can't exactly tell me how this test was done?
A I have to think about it. I don't remember.
Q Okay. How many kilograms in a newton?
A One kilogram is 9.8 newton.
Q Let me show you the first page of Exhibit 404 back at the knot slippage strength test. I'm going to shift gears on you here. There's a line at the 10-second point?
A Yes.
Q What is that line for, that vertical line?
A I do not remember.
Q Is someone looking at the slope before 10 seconds?
A I do not remember.
Q So in this test, the -- I guess you

238

don't remember. Anyway, the constant speed at the knot run-down, 1.5 millimeters per second, should be reflected in the data, right?
A Yes.
Q If you go to the table of the data results, see how Sample 1, coated, was .28, and sample 7, uncoated, was .28?
A Yes.
Q How do you explain that they were the same?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: I don't have any explanation.
BY MR. BONELLA:
Q And sample 3 was .26 and sample -- I'm sorry, sample 3, coated, was .26, and sample 8, uncoated, was .26. Can you explain that?
MR. TAMBURO: Same objection.
THE WITNESS: No.
BY MR. BONELLA:
Q Okay. The data where knot run-down force that's in the table, how did you generate those values?
A We calculated it as a force at the

239

moment when knot begins to slide down.
Q And how do you know when the knot begins to slide down?
A You look in the Figure 8, and you can clearly see that for as long as knot is intact, like in previous test, force goes up with the increase in time/distance.
As soon as force stops increasing with time, it means that knot started to run down.
Q Did you pick the peak of the curves, or was there an algorithm?
A Peak.
Q Peak?
A Yes.
Q You say that you also noted chatter variation, and knot run-down force was also noted.
Do you see that?
A Yes.
Q Did you determine chatter from this test that present the chatter results?
A When we presented the chatter in -- when we presented chatter in Table 5, it was kind of average of the amplitude in Figure 11 and amplitude in Figure 8.
Q It was the average of the amplitudes?

240

A I'm sorry, it was average of two chatters, right? Chatter in Figure 11 and chatter in Figure 8.
Q Okay, I'll come back to that then when we get to chatter.
(DePuy Mitek Exhibit Nos. 406 and 407 were marked for identification.)
BY MR. BONELLA:
Q I'll show you Exhibit 406. I believe this is the printout of the uncoated data from the knot run-down test.
I'll show you Exhibit 407. I believe this is the coated data from the knot run-down test. Does that look right?
A It looks correct.
Q Let's look at 407 for a minute, the coated values. If you look at the data under the first sample -- I guess for all the data that we look at, does the sample No. 1 always correspond with the Experiment No. 1 value in your charts?
A Yes.
Q The first column is F sub X. What is that?
A Again, it's the lateral force in X direction.

241

Q Which is the X direction?
A As we discussed, it's longitudinal of the force sensor -- along the longitudinal axis of the force sensor.
Q So it's into the brass rods on Figure 7?
A Yes.
Q And F sub Z?
A Is vertical force.
Q T is time and seconds?
A Time. Z is displacement. And, again, I don't remember what is sub F.
Q So in this -- once the -- was a preload done in this?
A It doesn't specify preload.
Q How about -- so a preload wasn't done?
A Correct.
Q Did you soak the sutures first?
A It doesn't specify, so we did not.
Q Now, for the knot run-down curves, can you -- before the onset of the run-down initiation, so before the peak is reached, can you use that data to determine pliability as you did for Table 1?
A It would give you a big, big error.
Q Why?

A Because of the same reasons as we discussed last time. Because if there is a loop, it measures friction because it's combination of friction and elastic properties. Because there was no substantial preload, you can really use it for pliability.
Q The duration in this, is that the time that the test took?
A Yes.
Q And the count, what is that?
A As last time, it's data rate, data frequency, how many data points. This count is higher than in test one because we needed to catch the peak, so we had higher frequency of data to catch the weighted peak of the run-down.
Q If you look at sample 7 in Exhibit 407 --
A 7, Exhibit 407, yes.
Q Coated, sample 7, it looks like it had the highest force?
A Yes.
Q Okay. And it was, I don't know, roughly .28, .29?
A Yes.
Q If we go to your data for knot run-down

test, sample 7 is 0.19 for coated.
A Yes.
Q How do you explain that?
A No explanation.
Q The next test, the friction test.
(A discussion was held off the record.)
MR. TAMBURO: Do you mind taking a 2-minute break?
MR. BONELLA: No.
THE VIDEOGRAPHER: This is the end of Tape 3. Off the record at 3:26:09.
(A break was taken.)
THE VIDEOGRAPHER: This is the beginning of Tape 4 in the deposition of Dr. Norm V. Gitis. On the record at 3:35:22.
BY MR. BONELLA:
Q Dr. Gitis, is the Table 2 in Exhibit 382 of knot strength any different than the knot strength data that you presented in Exhibit 381?
A No, it's the same.
Q I'd like to show you, this is going back to this knot strength slippage test for a minute.
A Yes.
Q That was done, according to your report, at a constant speed of 1.5 millimeters per second,

right?
A 1 millimeter per second, yes.
Q 1 or 1.5?
A For slippage, 1; for run-down, 1.5.
Q Sorry. Slippage was 1 millimeter per second?
A Right.
Q Okay. Let's look at the -- this is the slippage data, Exhibit 405, with a coated suture, right? If you look --
A Yes.
Q Look at this page here, and you look at time equals 4 seconds for sample 2 -- sample 1.
A Okay.
Q Sample 1, time of 4.002 -- wait.
A Yeah, 4 seconds.
Q For sample 1, the coated, time of 4.002 seconds, Z at a value of 115 --
A .33.
Q -- .33345, correct?
A Yes.
Q So if we're going at a constant velocity of 1 millimeter per second, Z is in millimeters, at 5 seconds we should have 116.3345, right, for Z?

A Yes.
Q Let's mark the page we just looked at as Exhibit 408.
(DePuy Mitek Exhibit No. 408 was marked for identification.)
BY MR. BONELLA:
Q If we go to this page and we go to the time of 5.0003 seconds --
A Yes.
Q -- the Z value is 115.199. Do you see that?
A Yes.
Q So the Z value from time equals 4.002, time equals 5.0003 for sample 1 actually went down.
A Yes.
Q Why is that?
A I don't remember. I'd have to look at the entire curve, but --
Q We'll just mark the page that we're looking at now as Exhibit 409, the page that has the 5.0003 seconds.
(DePuy Mitek Exhibit No. 409 was marked for identification.)
THE WITNESS: You're talking about one

258

BY MR. BONELLA:
Q Let me show you Exhibit 410 and 411. I think Exhibit 410 is the coated results from the friction test, and Exhibit 411 is the uncoated results from the friction test, right?
A Yes.
Q Let's look at Exhibit 410 for a minute. The data show, for example, one, under that it says radius. Do you see that?
A Yes.
Q What is that?
A It's a relevant parameter for this test, which is always shown.
Q What is the radius?
A It makes sense for the rotary motion, but not for the linear motion.
Q What is it?
A It's a radius of rotary motion, which makes no relation to -- has no relevance to the linear motion.
Q You didn't have the rotary motion driver here, did you?
A Right, this is why it was not supposed to be recorded.
Q What's set force? What is that?

259

A Set force was 2 newton, or 200 grams.
Q That's the force in the Z direction?
A Z force.
Q That's minus because it's pushing down?
A That's correct.
Q The next one is duration. What is that?
A It's just times 100 seconds.
Q The next one is --
A If you look at the data, it's 100 seconds.
Q Next one is entry something?
A We already discussed. It's number of data point, frequency of data acquisition.
Q First column is FX. What is that?
A Friction force.
Q Next column is FZ, what is that?
A Normal load.
Q So that's the one you were trying to keep constant?
A Yes.
Q Looks like it varied.
A Yes.
Q So it wasn't constant?
A If you measure normal load, it's never ever constant, so you try to maintain it as

260

constant as possible.
Q What happens if it's not constant?
A Pardon me?
Q If it's not constant, that means the upper suture is actually moving relative -- it's actually moving relative to the lower suture in a vertical direction, correct?
A Right, correct.
Q T is time and seconds?
A Yes.
Q In the distance, if the upper suture moves relative to the lower suture, that affects the friction force, right?
A Yes.
Q Z is what?
A Z is still vertical displacement in millimeters. So the original displacement, it's like zero, and you can calculate practically the rear depth of the suture. You have to do this test longer, for several minutes. You can wear out the suture, and Z will give you the dynamics of the depths of wear.
Q So Z just actually shows the relative motion of the upper suture to the lower suture?
A Yes.

261

Q F sub F, what is that?
A I'm sorry, like last time, I don't know.
Q F sub X and F sub F look like they're the same except -- the same magnitude, different in negative or positives. See that?
A I don't know.
Q You don't know?
A I have to consult my engineer. I don't remember what's is FF.
Q How about COF, what's that?
A That's a coefficient of friction, ratio of FX over FZ.
Q So FX divided by FC should give me COF?
A Yes.
Q Did you have to put any other parameters in the machine for the calculation of coefficient of friction, or is it just strictly that ratio?
A No, it's just ratio of friction force of a normal load.
Q See the average coefficient of friction data that you presented?
A Yes.
Q When you say average, did you take it across the whole time you did the sample, or did you just do it over a portion of the time?

262

A No, over the entire hundred seconds.
Q Okay. Why does it change initially, drop off right away, like it's the only curve where it drops?
A There is always some so-called run-in period or burnishing period. When you put two surfaces together, there's always some change in friction in the beginning until they get adjusted to each other.
Q Do you have any idea whether -- see how you got the average for point -- coated was .09, uncoated was 0.16?
A Yes.
Q Do you have any idea of how big of a difference that is relative to other sutures?
MR. TAMBURO: Objection, vague.
THE WITNESS: Relative to others sutures?
BY MR. BONELLA:
Q Like do sutures typically test in values of .08, or do they typically test in values of .8 or 2? Do you have any idea what the typical results are for a suture?
A I don't remember right now, but I do remember that we compared data to several

263

references, and data was of the same order of magnitude.
We compared to data of -- published data of several authors, and they had the same order of magnitude.
Q What do you mean they had the same order of magnitude?
A The friction is around .1.
Q Are you sure about that?
A Yes, I am.
Q Okay. And if it isn't?
A Huh?
Q If it isn't?
A Then somebody published wrong data.
Q Let's go back to this exhibit, 407 -- 410. 1.9, the first point, FX, and FZ is 199.386 of magnitude. If you divide them, my consultants here tell m you get 0.0095945.
A Right.
Q Which is not 0.139, which is the coefficient. If that math is correct, how do you explain why the coefficient of friction is different?
A I don't know, because as I said, I'm confused a little bit by this FF and FX. I have

264

to clarify this with my engineer what is FX and what is FF.
Q They're the same, so you said coefficient of friction was FX divided by FZ.
A Yes.
Q If this math is right, that means coefficient of friction is not FX divided by FZ. It's not F divided by FZ either.
A I have to clarify.
Q So you don't know how coefficient of friction was obtained?
A I know very well the coefficient of friction was obtained as a ratio, but I have to clarify columns FX and FF.
Q So you don't know what it is a ratio of?
A It's supposed to be a ratio of friction force over normal load.
Q Isn't FX the friction force, or FF the friction force?
A This will be my assumption.
Q They're the same value, so it shouldn't matter which one you use?
MR. TAMBURO: Objection, asked and answered.
BY MR. BONELLA:

265

Q Right?
A Right.
Q So sitting here today, you can't really tell me how you get coefficient of friction from this data?
A Right.
Q The next section is the chatter data. You said that the chatter data measured from both the knot run-down and suture-on-suture friction tests are summarized in Table 5 below.
Do you see that?
A Yes.
Q How did you determine the values that are in Table 5 from the two tests?
A If we talk amplitude of friction fluctuations from the knot run-down test and from amplitude of friction fluctuations from the suture-on-suture test, we just took the ratio as their average.
Q Let me back up. You say the variation in amplitude. Are you saying from each high point to each low point in each test you calculated it, or --
A No, no, no. We calculated not each and every point, but we calculated the average

amplitude of fluctuations.
Q Average amplitude of fluctuations. I don't understand what you mean.
A It consists of each and every point, but for the sake of Table 5, we talk only average from Figure 11 and average from Figure 8.
Q Are you saying you took the average from Figure 11 --
A Average amplitude. Average amplitude from Figure 8, average amplitude from Figure 11, and we took their average as amplitude for Table 5.
Q So you got the average amplitude for Figure 8 -- wait.
A Yeah, it's true.
Q It's difference in amplitudes, right? Chatter isn't the difference in amplitude?
A No, chatter is amplitude. Chatter is amplitude of fluctuations. So if you look -- for example, let's look at uncoated in Figure 11.
Uncoated in Figure 11 has amplitude from about .15 to about .17. It's .02. So amplitude is .02. Are you with me?
Q Are you saying basically you just looked at the graph, you drew a line that was along the

highest peaks here, and then looked at the line on the bottom and said the amplitude is .02?
A Yes.
Q How did you know where to draw the line? Like the beginning part goes down the curve. Did you omit that part?
A You don't really do it manually on the plot. You do it in the computer automatically, and --
Q Let me back up. Did the computer generate the values, or did you calculate them or get them from the graph for chatter?
A Amplitude of fluctuations is automatically produced by the computer.
Q By the computer, okay. Is that shown in the --
A Unfortunately not because secondary parameters. The recorded data in our software is only the original data, like force displacement, but what you calculate, statistical analysis, unfortunately, is not recorded.
Q Is it gone?
A Yeah.
Q You don't have it anymore?
A So this is what you have table for.

Q Is there some computer program that's in the machine that generates the difference in the amplitude for the Figure 8 and Figure 11 curves?
A Yes.
Q Can you tell me the math that is used to do that?
A The math will calculate the amplitude --
Q I mean, does it figure the average high point and the average low point, and then take the difference between the two, or does it take each high point with the next low point and take those differences and average them, or how does it work?
MR. TAMBURO: Objection, vague.
THE WITNESS: Can you please repeat?
BY MR. BONELLA:
Q Sure. One thing you could do, I just don't understand how the computer is doing this. One thing you could do is you could take this high point to the next low point, high point to low point, and you figure out that difference for each time and average them; or you can figure out what the high point was, the average high point and the average low point, and take the difference between those two.
A Yes.

Q Or there could be some other way you could do this. I don't know.
A Yeah, I do not remember. I'm sorry.
Q You don't know?
A No.
Q How about for determining it from the other figure, Figure 08, do you know how that was done?
A Same thing.
Q If you look at the Table 5 chatter data --
A Yes.
Q Do you know why sample 6 had a chatter data value of 0.012 for coated, which was greater than the uncoated suture chatter data value? Do you know why?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: Your question is whether -- I see it here. Yes, I see it.
BY MR. BONELLA:
Q Yeah. That's saying sample 6, coated, got a greater chatter value than sample 6, uncoated.
A Yes, I see it, yeah.

Q Can you explain why?
A No, I cannot.
Q The next test is the tissue drag tests, right?
A Yes.
Q It says two types of tests were performed, dragging the suture through the hole made with a needle, and dragging the suture between two tightly clamped pieces of leather.
A Yes.
Q In both cases, the upper end of the suture was attached to the UMT upper bracket, providing the well controlled motorized dragging action. Do you see that?
A Yes.
Q Do you see the curves in Figure 13?
A Yes.
Q Are those for the tests for dragging the suture through the hole made with the needle? Are those for the tests of dragging the suture between two tightly clamped pieces of leather?
A These curves are result of needle.
Q Are what?
A In the case -- in the second case, without the needle.

Q So Figure 13 is a tissue drag test without the needle test?
A Correct.
Q How about the Table 6 data?
A Same thing.
Q Where is the results of the tissue drag with the needle?
A We did not present them because average was the same.
Q So you did the tissue drag tests with the needle, you just didn't present the results?
A We started doing with the needle, then we switched to the clamp, we found no difference, and we continued with the clamp.
Q Yeah, okay. You did it with the needle, you didn't present the results. Do you still have the results?
A No, we do not.
Q What happened to them?
A We did not save them. I assume we overwrote the test file with the data from the clamp.
Q You overwrote -- you just said -- you just said you did the clamp first and the needle --

A No, no, we started from the needle, then we decided to switch to just clamp and get rid of the needle, and we found results are the same, so we discarded needle and proceeded only with clamping the suture between two pieces of leather.
Q Do you have any results at all from the needle testing that we can look at to assess your statement that the results were the same?
A No, we do not have.
Q The test with the needle, let's do the -- I'm sorry, let's do the clamp test first. If I can call it the clamp test, is that okay, the tissue drag clamp test?
A Uh-huh.
Q So that was done by clamping a suture between two pieces of leather; is that right?
A Yes.
Q And how is the tension controlled on the clamp?
A I'm sorry, which tension?
Q The clamping the suture between two pieces of leather, right?
A Yeah.
Q And the clamp is a metal clamp with a nut and bolt, right?

A Yes.
Q How are you controlling the tension or the forces that are applied by the clamp controlled by the nut and the bolt?
A We didn't control it.
Q You didn't control it, okay.
Now, so the suture is sandwiched, if you will, between two pieces of leather, right?
A That's correct.
Q And then the upper part of the suture is pulled; is that right?
A Pulled up, yeah.
Q And you used a 20 millimeter gauge length, right?
A Yes.
Q So is that the same for all samples?
A Is the same?
Q Was the 20 millimeter length the same for all samples for the clamp tissue drag?
A Yes.
Q And you did this test by pulling a constant rate. You did the tissue drag clamp test by pulling at a constant rate of 1 millimeter per second?
A Yes.

EXHIBIT 11

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-o-

DEPUY MITEK, INC., a Massachusetts Corporation,	: Civil Action No. 04-12457 PBS
Plaintiff,	:
-vs-	:
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LTD., a Private Limited Company of the United Kingdom,	: EXPERT DEPOSITION OF: ROBERT T. BURKS, M.D.
Defendants.	:

-o-

Location: Mariott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-o-

74

A. I would say it was probably 45 minutes plus ten minutes.
Q. Did you tie knots in each of the individual five sutures from suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. Yes.
Q. After you performed the tactile feel analysis and knot tie-down, as reflected in Exhibit 232, what did you do with the sutures that you tested?
A. I pitched them with the spools.
Q. You threw them out?
A. Yes.
Q. Did counsel ever instruct you to not throw away the samples?
A. No.
Q. Did counsel give you any instructions at all what to do with the samples once you performed the tests on them?
A. No.
Q. Did you throw them away at home or at the office?
A. At home.
Q. And then once you completed the tactile feel analysis and knot tie-down analysis and once you

75

threw away the sutures, what did you do next?
A. Well, as it regards this, I sent an e-mail to Sal and said here's what I thought.
Q. Do you have a copy of that e-mail?
A. Nope.
Q. What did you do with the e-mail that you sent to Sal after you concluded the tests?
A. What did I do with the e-mail? I didn't do anything with the e-mail. I hit "send".
Q. It's still on your computer?
A. I would doubt it's on the computer. I mean, just due to the volume, they don't keep three months or four months or whatever.
Q. Did you send it from work or home, the e-mail?
A. I don't know for sure.
Q. You don't know for sure?
A. No.
Q. Did you delete the e-mail you sent to Sal after you finished performing the tests?
A. I'm not sure I understand deleting the e-mail. I sent him an e-mail. I didn't purposefully delete any e-mail.
Q. Do you use Microsoft Outlook for your e-mails?

76

A. No.
Q. What program do you use for your e-mails?
A. At home it's a Comcast e-mail and then here it's a Group-Wise.
Q. But do you use -- what e-mailing system do you use at home? Is it AOL or Lotus Notes or Microsoft Outlook or a Yahoo account?
A. It's a Comcast.
Q. That's done on a personal computer?
A. Yes.
Q. What about in the office? What kind of e-mailing system do you use?
A. We call it Group-Wise.
Q. Is the e-mail account you have at home different than the one you have at the office?
A. Uh-huh.
Q. Did you look for the e-mail in response to the subpoena, Exhibit Number 231?
A. Yes. The e-mail -- I mean, my awareness of the e-mails is that they go back two or three weeks or so and then after that they just go into cyberspace.
Q. So you did not look for the e-mail in response to the subpoena, Exhibit 231?
A. No, because that was like three months

77

ago.
Q. When you say the e-mails go back two or three weeks and then go into cyberspace, you are referring to work e-mail or your home e-mail?
A. Well, primarily, I guess I'm referring to the work one. I don't use the home as much. So I don't. . .
Q. Do you remember what the e-mail said that you wrote to Sal after you performed the tests in Exhibit 232?
A. Pretty much what's in here. I just said, you know, sample A to me felt this way compared to sample B.
Q. Felt -- what word did you use to describe how suture A felt in relationship to suture B?
A. I don't remember specifically but, I mean, I probably used a word like "smoother".
Q. But you are not sure?
A. I'm not sure of the word.
Q. Did Sal send an e-mail back to you once you sent him the e-mail after completing the tests in Exhibit 232?
A. Not that I remember specifically.
Q. When was the next time you spoke to Sal after sending the e-mail on which you completed the